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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,228	10/12/2001	Lothar W. Kleiner	ARC 2427 N1	9517

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EXAMINER

WILLIAMSON, MICHAEL A

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 08/14/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/976,228

Applicant(s)

KLEINER ET AL.

Examiner

Michael A. Williamson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on or after 10/12/01.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,10-20,22 and 28-63 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,3,10-13,15,16,34-39,41,47,53,56,59,62 and 63 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims withdrawn from consideration are 14,17-20,22,28-33,40,42-46,48-52,54,55,57,58,60 and 61.

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DETAILED ACTION

Pending Claims

The pending claims in the instant application are 1, 3, 10-20, 22 and 28-63. The independent claims are 1, 14, 17, 40-46, 48, 49, 53-58, 60 and 61.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 3, 10-13, 15, 16, 34-39, 41, 47, 53, 56, 59, 62 and 63 are, drawn to a rate controlling membrane for a delivery device subjected to elevated temperature and subsequently incorporated into the delivery device and associated method of making said article, classified in class 424, subclass 449.
 - II. Claims 14, 42, 49, 57 and 58, drawn to a rate controlling membrane for a delivery device for drug delivery subjected to elevated temperature and subsequently incorporated into a delivery device after cooled and associated method of making said article, classified in class 424, subclass 449.

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- III. Claims 17-20, 22, 28-33, 40, 43, 45, 48 and 50-52, drawn to a rate controlling membrane for a deliver device having been allowed to relax, subjected to elevated temperature and subsequently incorporated into a delivery device and associated method of making, classified in class 424, subclass 449.
- IV. Claim 44, drawn to a rate controlling membrane for drug delivery having been dried, subjected to elevated temperature and subsequently incorporated into a delivery device, classified in class 424, subclass 449.
- V. Claim 46, drawn to a rate controlling membrane for drug delivery having been allowed to relax, having been dried, subjected to elevated temperature and subsequently incorporated into a delivery device, classified in class 424, subclass 449.
- VI. Claim 54, drawn to a method of making a rate controlling membrane subsequently incorporated into a delivery device with low water variability, classified in class 424, subclass 449.
- VII. Claim 55, drawn to a rate controlling membrane with decreased variability of water uptake, classified in class 424, subclass 443.

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VIII. Claim 60, drawn to an rate controlling membrane subjected to elevated temperature (annealing) having a more stable water uptake, classified in class 424, subclass 443.

IX. Claim 61, drawn to a rate controlling membrane subjected to elevated temperature having decreased water uptake, classified in class 424, subclass 443.

2. The inventions are distinct, each from the other because of the following reasons: Inventions VII-IX and I-VI are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as a food wrapping film and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. Inventions I-IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case the different inventions are not disclosed as capable of being used together and they have different effects such as the speed in which the drug is dispensed.

4. Inventions I-V and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by a materially different process such as film casting.

5. Because these inventions are distinct for the reasons given above and the search required for any one of Groups I-VIII is not required for Group IX, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Mr. Samuel Webb on August 11, 2003 a provisional election was made with traverse to prosecute the invention of Group I,

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claims 1, 3, 10-13, 15, 16, 34-39, 41, 47, 53, 56, 59, 62 and 63. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14, 17-20, 22, 28-33, 40, 42-46, 48-52, 54, 55, 57, 58, 60 and 61 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1, 3, 10-13, 15, 16, 34-39, 47, 59, 62, and 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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10. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1-xzc recites the broad recitation controlling membrane, and the claim also recites the membrane polymer which is the narrower statement of the range/limitation.

11. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There lacks antecedent basis for the recitation of "the drug containing chamber".

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Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1, 3, 10-13, 15, 16, 34-39, 41, 47, 53, 56, 59, 62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peery et al. (U.S. Patent 5,728,396) in view of Jiang (U.S. Patent 5,446,108).

Peery et al. discloses a rate controlling membrane comprising polyurethane or polyether blocked amides copolymers subsequently incorporated into a delivery device containing the drug leuprolide (see Abstract, Figures 1 and 2 and col. 5, line 66 to col. 6, line 61). Peery et al. does not disclose that the rate controlling membrane is subjected to an elevated temperature below the melting temperature for a predetermined time and annealed.

Jiang discloses polyamide polymers similar to those taught by Peery et al. used in the making of surgical devices such as drug delivery devices that are subjected to an elevated temperature below the melting temperature for a predetermined time which is annealing, and subsequently incorporated into a delivery device (see col. 3, line 31 to

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col. 4, line 7 and col. 5, lines 14-50). Jiang disclose that the membrane is annealed (see col. 4, lines 6-7) causing the membrane to shrink thereby returning the membrane to its most relaxed state which is equivalent to Applicant's use of the specific temperatures and time periods used (see Instant application, Field of the Invention). Therefore, it would have been obvious to one of ordinary skill in the art to use any temperature and predetermined time including that of the instant claimed invention to anneal the membrane to return it to its most relaxed state in the absence of a factual showing of criticality of the times and temperatures claimed or a showing of unexpected results.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

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Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1, 3, 10-13, 15, 16, 34-39, 41, 47, 53, 56, 59, 62 and 63 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 10-14, 16 and 35 of U.S. Patent No. 6,375,978.

Although the conflicting claims are not identical, they are not patentably distinct from each other because being silent regarding the drug containing component does not mean that it is not present since the language used is open. Therefore, it would have been obvious to included a drug since the preamble states that the invention is for the purpose of drug delivery.

16.

Crystal Mall 1 Facsimile Center

A facsimile center has been established in Crystal Mall 1, room 7C10. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 308-4556. The new location should be used in all instances when faxing any correspondence to Group 1600. Use of the new

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Crystal Mall 1 center will facilitate rapid delivery of materials to the Group. The faxing of all papers must conform with the notice published in the Official Gazette, 1096 O.G. 30 (November 15, 1989).

17. Any inquiry concerning this communication or earlier communication from the examiner should be directed to Michael A. Williamson whose telephone number is (703) 308-1235.



Michael A. Williamson
Patent Examiner
Group 1610

Williamson030811
August 12, 2003